HRP-813 | 03/01/2024

**FORM: Site Modification**

Use to request a modification to previously approved site activities[[1]](#footnote-1)

**basic information**

|  |  |
| --- | --- |
| **Basic Study Information** | **Study Details** |
| IRB Number: | Click or tap here to enter text. |
| Study Title: | Click or tap here to enter text. |
| Short Title: | Click or tap here to enter text. |
| Site Investigator: | Click or tap here to enter text. |
| Site Primary Contact: | Click or tap here to enter text. |

**Site Enrollment Status**

**Check all that are true:**

☐ No subjects have been enrolled to date.

☐ Subjects are currently enrolled.

☐ The study is permanently closed to enrollment at my site.

☐ All subjects enrolled at my site have completed all study related interventions and interactions, including interventions and interactions related to collection of long-term follow-up data.

☐ No additional identifiable private information about the subjects is being obtained by me.

**Notification of subjects**

☐ Current subjects will be notified of these changes.

☐ Former subjects will be notified of these changes.

If either is checked, ensure that the submitted documents describe how current or former subjects will be notified): Click or tap here to enter text.

**Site information**

Provide the following documents when they exist or are applicable and have been modified:

* Point-by-point response *(For a response to modifications to secure approval, deferral, or disapproval)*
* Evaluation of any Related Financial Interest.
* Written materials to be provided to or meant to be seen or heard by subjects at your site
  + Evaluation instruments and surveys
  + Advertisements *(printed, audio, and video)*
  + Recruitment materials and scripts
  + Consent documents *(The IRB does not require an informed consent document for HUD use.)*
  + If consent will not be documented in writing, a script of information to be provided orally to subjects
  + Foreign language versions of the above
* Site supplement to the main protocol

**Investigator Acknowledgement**

I will conduct this protocol in accordance with requirements in HRP-103 - INVESTIGATOR MANUAL.

**Investigator signature**

Date of Signature: Click or tap here to enter text.



1. This document satisfies AAHRPP element I9 [↑](#footnote-ref-1)